

## PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner  
US Department of Commerce  
United States Patent and Trademark  
Office, PCT  
2011 South Clark Place Room  
CP2/5C24  
Arlington, VA 22202  
ETATS-UNIS D'AMERIQUE  
in its capacity as elected Office

Date of mailing (day/month/year) 21 November 2000 (21.11.00)	
International application No. PCT/US00/08669	Applicant's or agent's file reference 16303-76-2PC
International filing date (day/month/year) 31 March 2000 (31.03.00)	Priority date (day/month/year) 01 April 1999 (01.04.99)
Applicant SARRIS, Andreas, H. et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
30 October 2000 (30.10.00)

☐ in a notice effecting later election filed with the International Bureau on:  
\_\_\_\_\_

2. The election ☒ was

☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Diana Nissen Telephone No.: (41-22) 338.83.38
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# INTERNATIONAL SEARCH REPORT

Int. appl. No.

PCT/US 00/08669

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K9/127 A61P35/00 A61K31/475

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 741 516 A (WEBB MURRAY S ET AL) 21 April 1998 (1998-04-21) cited in the application the whole document	1-68, 70-77
X	US 5 595 756 A (BALLY MARCEL B ET AL) 21 January 1997 (1997-01-21)  column 3, line 55 -column 5, line 40 column 7, line 40 -column 8, line 22; example 1 claims 1-10	1-8, 11-40, 43-62, 64-68, 70-74



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

\* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

31 August 2000

Date of mailing of the international search report

07/09/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
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Authorized officer

Muller, S

# INTERNATIONAL SEARCH REPORT

Int. Application No.

PCT/US 00/08669

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>US 5 714 163 A (COX GERRY ET AL)  3 February 1998 (1998-02-03)  cited in the application</p> <p>column 4, line 44 -column 5, line 53  column 6, line 17 -column 6, line 51;  example 1  claims 1-5</p>	<p>1-8,  11-40,  43-62,  64-68,  70-74</p>
X	<p>US 4 952 408 A (RAHMAN AQUILUR)  28 August 1990 (1990-08-28)</p> <p>column 2, line 30 -column 4, line 29  claims 1-11</p>	<p>1-6,  13-30,  60-62,  64-68,  70-77</p>
A	<p>US 5 165 922 A (GOODMAN GARY E ET AL)  24 November 1992 (1992-11-24)  column 7, line 30 - line 68</p>	<p>1-77</p>

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/08669

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5741516	A	21-04-1998	US 5543152 A	06-08-1996
			US 5814335 A	29-09-1998
			AU 2709495 A	15-01-1996
			CA 2193502 A	28-12-1995
			WO 9535094 A	28-12-1995
			EP 0804159 A	05-11-1997
			JP 10501534 T	10-02-1998
US 5595756	A	21-01-1997	NONE	
US 5714163	A	03-02-1998	AU 684209 B	04-12-1997
			AU 2998495 A	19-01-1996
			CA 2191077 A	04-01-1996
			EP 0734252 A	02-10-1996
			WO 9600057 A	04-01-1996
			US 5888537 A	30-03-1999
US 4952408	A	28-08-1990	AT 103172 T	15-04-1994
			AU 625308 B	09-07-1992
			AU 3742489 A	12-12-1989
			CA 1339077 A	29-07-1997
			DE 68914154 D	28-04-1994
			DE 68914154 T	20-10-1994
			DK 279890 A	23-11-1990
			EP 0416014 A	13-03-1991
			IE 64513 B	09-08-1995
			JP 3504381 T	26-09-1991
			WO 8911292 A	30-11-1989
US 5165922	A	24-11-1992	CA 2083391 A	23-11-1991
			EP 0575321 A	29-12-1993
			HU 63340 A	30-08-1993
			WO 9117770 A	28-11-1991
			ZA 9103879 A	25-03-1992

09/937674

## PATENT COOPERATION TREATY



PCT

REC'D 10 JUL 2001

WIPO

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 16303-762PC		<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/08669	International filing date (day/month/year) 31/03/2000	Priority date (day/month/year) 01/04/1999	
International Patent Classification (IPC) or national classification and IPC A61K9/127			
Applicant INEX PHARMACEUTICALS CORP. et al.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 8 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"><li>I <input checked="" type="checkbox"/> Basis of the report</li><li>II <input type="checkbox"/> Priority</li><li>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li><li>IV <input type="checkbox"/> Lack of unity of invention</li><li>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li><li>VI <input type="checkbox"/> Certain documents cited</li><li>VII <input type="checkbox"/> Certain defects in the international application</li><li>VIII <input checked="" type="checkbox"/> Certain observations on the international application</li></ul>			
Date of submission of the demand 30/10/2000		Date of completion of this report 06.07.2001	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized officer Pregetter, M Telephone No. +49 89 2399 8719 	

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/US00/08669

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):
- Description, pages:**

1-27 as originally filed

**Claims, No.:**

1-77 as originally filed

**Drawings, sheets:**

1/2-2/2 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

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☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 1-67, 75-77, concerning industrial applicability.

because:

☒ the said international application, or the said claims Nos. 1-67, 75-77 relate to the following subject matter which does not require an international preliminary examination (*specify*):  
**see separate sheet**

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)

Yes: Claims 31-59, 68-70

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	No:	Claims	1-30, 60-67, 71-77
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-77
Industrial applicability (IA)	Yes:	Claims	68-74
	No:	Claims	

2. Citations and explanations  
**see separate sheet**

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:  
**see separate sheet**



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/08669

**Re Item III**

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 1-67 and 75-77 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

**Re Item V**

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: US-A-5 741 516 (WEBB MURRAY S ET AL) 21 April 1998 (1998-04-21)  
cited in the application

D2: US-A-5 595 756 (BALLY MARCEL B ET AL) 21 January 1997 (1997-01-21)

D3: US-A-5 714 163 (COX GERRY ET AL) 3 February 1998 (1998-02-03) cited  
in the application

D4: US-A-4 952 408 (RAHMAN AQUILUR) 28 August 1990 (1990-08-28)

D5: US-A-5 165 922 (GOODMAN GARY E ET AL) 24 November 1992 (1992-  
11-24)

2. The subject-matter of present claims 1, 60 and 64 is not novel according to Article 33(2) PCT.
  - 2.1. Methods for the treatment of cancer in mammals, especially humans, with liposome-encapsulated vinca alkaloids are well known in the art. Vinca alkaloids are already used for all stages of the treatment of cancer. It goes without saying that an equal treatment can be, and is often, given for the original treatment and for the treatment after relapse.  
It is even more obvious that a transformed cancer (as defined in present claim 60) is treated with the "normal" therapy.
  - 2.2. Document D1 already discloses a method of treatment for cancer comprising the administration of liposome encapsulated vinca alkaloids.

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International application No. PCT/US00/08669

Document D1 discloses liposomes comprising sphingomyelin and cholesterol or liposomes comprising DSPC and cholesterol. The liposomal interior has a pH less than that of the liposomal exterior. The treatment of mice having P388 tumours is described in examples III and IV. Example VIII discloses the treatment of A431 tumours.

Document D2 discloses a method of treatment for cancer comprising the administration of liposome encapsulated vinca alkaloids (cf. claims 9 and 10 and examples 2 and 3).

Document D3 describes the treatment of mice with implanted Lymphosarcoma tumour cells by the administration of liposome (DSPC, cholesterol) encapsulated vinca alkaloids (vincristine)(examples).

Document D4 discloses a method to treat a neoplasia in a mammal wherein 1.2-1.6mg of vinca alkaloid per m<sup>2</sup> in humans is to be administered (col.3, l.63-68). The vinca alkaloids are encapsulated in liposomes (col.2, l.58 - col.3, l.20).

2.3. The dependent claims 2-30, 61-63, and 65-67 do not contain any features which, in combination with the features of any claim to which they refer, might establish novelty and an inventive step over D1-D5 (Articles 33(2) and 33(3) PCT). These claims are only allowable in combination with patentable independent claims.

3.1. The subject-matter of present claim 31 is not inventive according to Article 33(3) PCT.

Document D4, which is considered to represent the most relevant state of the art, discloses (cf. claim 10) a method of treatment for non-Hodgkin's Lymphoma from which the subject-matter of claim 31 differs in that the presence of cardiolipin in the composition to be administered is disclaimed.

However, a disclaimer can only be used to render a non-obvious teaching novel over a accidentally novelty destroying prior art. A disclaimer cannot be used to establish an inventive step. There is no reason to believe that the absence of cardiolipin has any surprising effect.

Furthermore, the documents D2 and D3 teach the encapsulation of vincristine in liposomes free of cardiolipin (cf. 2.2.). It is general knowledge and stressed in both D2 (col.1, l.53-60) and D3 (col.1, l.36-37) that vincristine is used to treat non-Hodgkin's Lymphoma. A person skilled in the art would use the liposomes disclosed in D2 and D3 not only to treat tumours in animal models, but also for the

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International application No. PCT/US00/08669

treatment of non-Hodgkin's Lymphoma (the main application of vincristine).

- 3.2. The dependent claims 32-59 do not contain any features which, in combination with the features of any claim to which they refer, might establish an inventive step over D1-D5 (Article 33(3) PCT). These claims are only allowable in combination with patentable independent claims.
4. The subject-matter of claims 68 and 70 is not inventive according to Article 33(3) PCT.  
The presence of instructions is a usual occurrence in a kit for use in the treatment of a disease. Since components useful in the preparation of liposome-encapsulated vinca alkaloid (cf. item VIII 2.) and stable formulations of liposome-encapsulated vinca alkaloids are already known in the art (cf. point 2.2.), the presence of instructions cannot render the subject-matter of claims 68 and 70 inventive.
- 5.1. The subject-matter of claim 71 is not novel according to Article 33(2) PCT.  
Document D4 already discloses a method of treating non-Hodgkin's Lymphoma (claim 10). This method comprises the administration of a pharmaceutical composition comprising a liposome-encapsulated vinca alkaloid selected from the group comprising vincristine. Consequently, liposome-encapsulated vincristine has already been used for the manufacture of a pharmaceutical composition for the treatment of non-Hodgkin's Lymphoma.
- 5.2. The dependent claims 72-77 do not contain any features which, in combination with the features of any claim to which they refer, might establish novelty and an inventive step over D1-D5 (Articles 33(2) and 33(3) PCT). These claims are only allowable in combination with patentable independent claims.
6. For the assessment of the present claims 1-67 and 75-77 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/US00/08669

and the use of such a compound for the manufacture of a medicament for a new medical treatment.

**Re Item VIII**

Certain observations on the international application

1. Although claims 1, 38, 60 and 64 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

Hence, claims 1, 38, 60 and 64 do not meet the requirements of Article 6 PCT.

2. The subject-matter of claim 68 is not clear (Article 6 PCT). The term "useful" has no precise meaning in the art. "Useful" components in the preparation of a liposome-encapsulated vinca alkaloid are for example: a vial, water, lipids, a stirrer, a puffered solution, ... .
3. The terms "Rituxan", "Oncolym" and "Bexxar", employed in claims 26 and 58 and appearing to be registered trade marks have no precise meaning as they are not internationally accepted as standard descriptive terms, thereby rendering the definition of the subject-matter of these claims 26 and 58 unclear (Article 6 PCT).
4. The subject-matter of claims 75-77 is not clear (Article 6 PCT). These claims define uses and refer to claim 65. Claim 65 is a method claim, not a use claim.

**PCT**WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau

## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>7</sup> : <b>A61K 9/127, A61P 35/00, A61K 31/475</b>		<b>A1</b>	(11) International Publication Number: <b>WO 00/59473</b>
			(43) International Publication Date: 12 October 2000 (12.10.00)
(21) International Application Number: <b>PCT/US00/08669</b>		(74) Agents: FOLLETTE, Peter, J. et al.; Townsend and Townsend and Crew LLP, 8th floor, Two Embarcadero Center, San Francisco, CA 94111 (US).	
(22) International Filing Date: 31 March 2000 (31.03.00)			
(30) Priority Data: 60/127,444 1 April 1999 (01.04.99) US 60/137,194 2 June 1999 (02.06.99) US		(81) Designated States: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).	
(71) Applicant (for all designated States except US): INEX PHARMACEUTICALS CORP. [CA/CA]; 100-8900 Glenlyon Parkway, Glenlyon Business Park, Burnaby, British Columbia V5J 5J8 (CA).			
(72) Inventors; and (75) Inventors/Applicants (for US only): SARRIS, Andreas, H. [US/US]; Apartment 715, 7200 Alameda Road, Houston, TX 77054 (US). CABANILLAS, Fernando [US/US]; Box 68, 2316 Shakespeare Road, Houston, TX 77030 (US). LOGAN, Patricia, M. [CA/CA]; 462 Aubrey Place, Vancouver, British Columbia V5V 2T6 (CA). BURGE, Clive, T., R. [CA/CA]; 917 Damelart Way, Brentwood Bay, British Columbia V8M 1C2 (CA). GOLDIE, James, H. [CA/CA]; 2558 W 7th Avenue, Vancouver, British Columbia V6K 1Y9 (CA). WEBB, Murray, S. [CA/CA]; 8467 Sunset Drive, Delta, British Columbia V4C 3Y5 (CA).		<b>Published</b> <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(54) Title: COMPOSITIONS AND METHODS FOR TREATING LYMPHOMA			
(57) Abstract <p>This invention provides methods for treating neoplasias in a mammal. In particular, the invention provides methods for treating various types of lymphomas, including relapsed forms of non-Hodgkin's Lymphoma. These methods involve the administration of liposome-encapsulated vinca alkaloids, e.g., vincristine, to a mammal with a lymphoma.</p>			

*FOR THE PURPOSES OF INFORMATION ONLY*

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
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EE	Estonia	LR	Liberia	SG	Singapore		

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>16303-76-2PC</b>	<b>FOR FURTHER ACTION</b> <small>see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.</small>	
International application No. <b>PCT/US 00/ 08669</b>	International filing date (day/month/year) <b>31/03/2000</b>	(Earliest) Priority Date (day/month/year) <b>01/04/1999</b>
Applicant  <b>INEX PHARMACEUTICALS CORP. et al.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of Invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☒ None of the figures.

## INTERNATIONAL SEARCH REPORT

International Application No

P 00/08669

A. CLASSIFICATION OF SUBJECT MATTER  
 IPC 7 A61K9/127 A61P35/00 A61K31/475

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 741 516 A (WEBB MURRAY S ET AL) 21 April 1998 (1998-04-21) cited in the application the whole document	1-68, 70-77
X	US 5 595 756 A (BALLY MARCEL B ET AL) 21 January 1997 (1997-01-21)  column 3, line 55 -column 5, line 40 column 7, line 40 -column 8, line 22; example 1 claims 1-10	1-8, 11-40, 43-62, 64-68, 70-74

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

31 August 2000

Date of mailing of the international search report

07/09/2000

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## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/08669

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 714 163 A (COX GERRY ET AL) 3 February 1998 (1998-02-03) cited in the application  column 4, line 44 -column 5, line 53 column 6, line 17 -column 6, line 51; example 1 claims 1-5 ---	1-8, 11-40, 43-62, 64-68, 70-74
X	US 4 952 408 A (RAHMAN AQUILUR) 28 August 1990 (1990-08-28)  column 2, line 30 -column 4, line 29 claims 1-11 ---	1-6, 13-30, 60-62, 64-68, 70-77
A	US 5 165 922 A (GOODMAN GARY E ET AL) 24 November 1992 (1992-11-24) column 7, line 30 - line 68 -----	1-77

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/08669

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5741516	A	21-04-1998	US 5543152 A	06-08-1996
			US 5814335 A	29-09-1998
			AU 2709495 A	15-01-1996
			CA 2193502 A	28-12-1995
			WO 9535094 A	28-12-1995
			EP 0804159 A	05-11-1997
			JP 10501534 T	10-02-1998
US 5595756	A	21-01-1997	NONE	
US 5714163	A	03-02-1998	AU 684209 B	04-12-1997
			AU 2998495 A	19-01-1996
			CA 2191077 A	04-01-1996
			EP 0734252 A	02-10-1996
			WO 9600057 A	04-01-1996
			US 5888537 A	30-03-1999
US 4952408	A	28-08-1990	AT 103172 T	15-04-1994
			AU 625308 B	09-07-1992
			AU 3742489 A	12-12-1989
			CA 1339077 A	29-07-1997
			DE 68914154 D	28-04-1994
			DE 68914154 T	20-10-1994
			DK 279890 A	23-11-1990
			EP 0416014 A	13-03-1991
			IE 64513 B	09-08-1995
			JP 3504381 T	26-09-1991
			WO 8911292 A	30-11-1989
US 5165922	A	24-11-1992	CA 2083391 A	23-11-1991
			EP 0575321 A	29-12-1993
			HU 63340 A	30-08-1993
			WO 9117770 A	28-11-1991
			ZA 9103879 A	25-03-1992